



70063-00004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho

Art Unit: 1617

Serial No.: 10/599,779

Examiner: Gina Yu

Filed: 06/28/2007

Title: SKIN LIGHTENING METHOD

Declaration Under 37 CFR Section 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

I, the undersigned Sherilee J. Backman, declare and say:

1. I am a cosmetic chemist with over twenty years of technical experience in the cosmetics industry. My expertise includes formulating new products, including skincare, color, cosmetics, hair care, OTC drugs, and many other product types; assisting in and troubleshooting cosmetics manufacturing; providing technical documentation supported by experimental data; and communicating with customers as a liaison for various interest groups. I studied Biology as an undergraduate at Rensselaer Polytechnic Institute in Troy, NY; I later graduated from Rutgers College, Rutgers University, in NJ with a B.A. in Political Science. I have served as an Adjunct Professor for core courses in the Masters Program in Cosmetic Science at Fairleigh Dickinson University in Teaneck, NJ, and hold several patents in the area of novel raw material applications in cosmetic formulations. Further details concerning my academic

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training, work experience, and activities are presented in my résumé attached as Exhibit A to the present declaration.

2. I have reviewed the present patent application, Serial No. 10/599,779, Skin Lightening Method. I have also reviewed U.S. Patent No. 4,296,130 ("Herschler") and the office action of the present application dated November 13, 2009 discussing Herschler and other prior art references.

3. I reviewed the Herschler patent to determine whether it might disclose the concept of using methylsulfonylmethane (MSM) to lighten skin tone. Herschler discloses other uses of MSM for treating the skin, but does not in any way disclose or suggest that MSM is capable of lightening a subject's skin tone.

4. I reviewed the office action dated November 13, 2009 concerning the rejection of claim 1 for obviousness over Herschler, Webster's Ninth New Collegiate Dictionary's definition of "complexion," and International Patent Publication WO/1994/005479 ("Salim"). The examiner found Herschler's disclosure that MSM could be used to "beautify the complexion," together with a definition of "complexion" as "the color or appearance of skin," would have made it obvious to use MSM to lighten skin tone. This finding does not accurately reflect what would have been obvious to a cosmetic chemist when the present patent application was first filed as an international application in April 2005, as more fully explained below.

5. Herschler's use of the word "complexion" is limited only to the phrase "beautify the complexion." A cosmetic chemist of ordinary skill would not have understood "beautify the complexion" as used by Herschler to mean "lightening the skin tone." Instead, one of ordinary skill would have believed that to beautify the complexion meant to improve the skin's appearance by a cosmetic effect such as softening and smoothing. Herschler is limited to disclosing cosmetic effects of MSM, such as

softening and smoothing. In contrast, lightening the skin tone is more of a physiological effect, is not disclosed or discussed by Herschler at all, and is of a different nature than softening and smoothing.

6. It is self-evident from his disclosure that Herschler had not conceived of using MSM for skin lightening or brightening and therefore could not have used the phrase "beautify the complexion" to refer to any such effect. For example, Herschler does not mention vitiligo, hyperpigmentation, or any other disease affecting skin color, at all. His patent is focused on the stabilization of urea (carbamide) by combining it with MSM, and using this combination to "beautify the complexion" by softening and smoothing the skin. In column 3 of his patent, he writes "An object is to provide a stable, neutral vehicle for pharmaceuticals, which vehicle has no interfering or undesirable pharmacological activity." Furthermore, if Herschler were interested at all in skin lightening, he would have mentioned hydroquinone, or some other known skin lightening agent, in his table of "actives" in column 13. The fact that he mentions no such agent evidences his lack of knowledge or interest in skin lightening as an effect of his cosmetic compositions.

7. Even in isolation, that is, outside of the context of Herschler, to "beautify" the skin complexion would not have been understood as meaning or suggesting lightening of skin tone to a cosmetic chemist, because various cosmetics are known to both lighten and darken skin in pursuit of a more beautiful complexion. That is, to "beautify" does not imply either lightening or darkening of skin tone. Instead, to refer to making the overall skin tone lighter, a cosmetic chemist would have used the terms "lightening" or "brightening" the skin tone or complexion.

8. I have experience in the production and use of products for skin lightening and brightening, including products based on hydroquinone, ascorbic acid and its derivatives (including but not limited to various ascorbyl phosphates, ascorbyl glucoside, and other ascorbyl esters), kojic acid, and plant extracts including but not limited to those of arbutin, licorice and mulberry. These ingredients and combinations thereof, like MSM, are used to lighten skin tone. As a cosmetic chemist developing skin lighteners, I considered various alternatives and prospective substances to achieve skin lightening, without discovering any reference to MSM as a prospective skin lightener. In addition, the Herschler and Salim references contain nothing that would have led me to consider trying MSM as a prospective skin lightening agent. There is nothing in these references or otherwise reported in the prior art that I am aware of to suggest that MSM might have been expected to possess skin lightening properties. MSM's skin lightening effects as first reported by the inventor of the present application would therefore not have been considered expected or predictable at the time these effects were first reported by her in the present application.

9. Claim one of the present application is limited to "at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months." The references Herschler and Salim do not specifically disclose this dose regimen. Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as healing injured skin, in combination with a sulfur-containing amino acid. Salim does not disclose a specific duration of treatment, a dose per unit of body weight, or a skin lightening effect. A cosmetic chemist of ordinary skill would understand Salim as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg three or four times daily, or smaller doses more frequently), in combination with one or more sulfur-containing amino acids in the same dosage range. For a relatively small 45 kg adult female, this equates to a maximum dose of MSM in the range of 33 to 44

mg/kg/day, which is much less than the at least 133 mg/kg/day specified in claim 1 of the present application.

10. One of ordinary skill reading Herschler and Salim would not have been motivated to discover the higher dose range specified in claim 1, for several reasons. First, lower doses were already known to be effective for all known cosmetic and therapeutic applications, as demonstrated by the Herschler and Salim references. Second, there was no suggestion that higher doses of MSM would produce any beneficial effect, much less skin lightening. One of ordinary skill would therefore have had no apparent reason to experiment with higher doses.

11. In addition, the Salim reference is focused on the synergistic effect of sulfur-containing amino acids with MSM, predominately but not exclusively by topical administration. Most important, Salim demonstrated that increasing the concentration of MSM alone does not provide any additional benefit in reducing tissue injury. Specifically, in the tables reported on pages 11 and 13 of Salim, no additional benefit is shown for increasing concentration of MSM past 5% in ethanol administered orally. Therefore, Salim provides no incentive to experiment with higher doses, and if anything, might have discouraged such experimentation by reporting that increased concentrations of MSM provide no additional benefit.

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12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: _____

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Respectfully submitted,

Date:

January 22, 2010

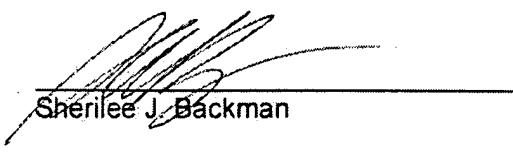

Sherilee J. Backman

EXHIBIT “A”

Sherilee J. Backman

64 Grove Street Brattleboro, VT 05301 T. 802-258-9005 C. 732-801-7542 personalcare@gmail.com

Qualifications Over twenty years of technical experience in the cosmetics industry. Strong skills in formulating very creative and innovative products, troubleshooting the manufacturing process, as well as in customer communication and oral and written presentations. Experienced in formulating skincare, color, cosmetics, haircare, OTC drugs, and many other products. Experienced in start-to-finish personal product development and commercialization. Adept at management, ingredient sales and distribution, and targeted marketing.

Experience *2008–Current Venus of Vermont, Inc. Brattleboro, VT*

Technical Director

- Provide technical, sales and marketing expertise to select customers in the cosmetics and nutraceuticals arenas.

2004–2007 DKSH North America, Inc. Baltimore, MD

Business Unit Manager, Personal Care & Food Ingredients

- Managed personal care and cosmetic, and food, beverage and nutraceutical ingredient product lines.
- Performed sales, marketing and technical services.
- Expanded client and product bases with multi-tiered marketing and sales strategies.
- Visited key customers, established subdistributors, agents and strategic alliances, and contracted materials suppliers.
- Covered territory of US, Canada and Central America.
- Coordinated services to multinational clients; established global pricing and resolved regulatory compliance issues.
- Sourced novel and unique raw materials for representation; found and evaluated principals and materials; helped develop and shared marketing and technical information; wrote contracts; participated on the DKSH PCI New Product Development team.
- Proposed establishment of a regional technical service division.
- Wrote and monitored divisional budgets totaling above \$3 million in sales.
- Established and coordinated logistics efforts; established warehousing and built costs into product price positions.
- Communicated with international colleagues daily.
- Developed advertising and company brand image awareness.
- Increased gross sales in cosmetics materials by nearly 60% within two years.
- Expanded cosmetic ingredient portfolio exponentially within two years.

1997–2004 SJH Consulting, Inc. Germantown, MD

President

- Provide cosmetic formulations, raw materials evaluations, and sourcing for goods and services.
- Guide product commercialization and production.
- Assist start-ups any way possible.

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1998–2004 *Fairleigh Dickinson University* *Hackensack, NJ*

Adjunct Professor

- Teach Skin Care and Hair Care Formulation, and Raw Materials Evaluation, lecture courses for the School of Natural Sciences Master's program in cosmetic sciences.

1998–2000 *Cosmetech Laboratories, Inc.* *Fairfield, NJ*

Vice President

- Provided formulation and raw material evaluation guidance to customers and staff.
- Promoted customer relations with innovative technology.

1996–1997 *Presperse Inc.* *Piscataway, NJ*

Technical Manager

- Managed full-service supplier laboratory and staff.
- Oversaw QC, applications, technical service and sampling functions.
- Designed and oversaw experimental raw material evaluations.
- Established standard operational procedures in the laboratory.

1993–1996 *Rona®/EM Industries* *Hawthorne, NY*

Senior Applications Chemist

- Provided prototype formulations and oversaw substantiation testing.
- Devised technical programs for new and existing raw materials.
- Helped establish materials specifications.
- Provided technical service to customers.
- Wrote and assessed supplier literature.

Affiliations and Honors

SCC; CTFA Sunscreen Task Force and Steering Committee. RPI Honors List, Rutgers Deans List; member, Alpha Sigma Lambda Honors Fraternity; NYSCC Chapter Historian, patent holder.

Skills

- Successfully pitch product approaches and materials to customers.
- Create innovative and patent-able product formulations
- Provide assistance in start-to-finish product commercialization.
- Formulate, both from scratch and from prototype, a wide variety of cosmetic systems throughout the range of skincare, haircare, color cosmetic and treatment products (q.v. attached listing).
- Color-matching.
- Trouble-shoot production/manufacturing process.
- Provide customer technical support, including developing presentations.
- Versatile in computer software applications.
- Able to perform accurate benchwork quickly and efficiently.
- Coordinate multiple groups of people and projects.

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Products developed include:

Skin Care	daily use moisturizing creams and lotions for body, hands, face, feet, undereye, etc. moisturizing gels and serums water-in-oil and water-in-silicone barrier creams and lotions body mousses alpha- and beta-hydroxy products mixed emulsions liquid crystal emulsions low-energy emulsions spray emulsions baby products cleansing milks, creams, toners NPA-approved and certified organic products
Hair Care	shampoos 2-in-1 and 3-in-1 shampoos conditioners hair repair and glossing products hair gels hair sprays (natural pump and aerosol) hair mousses perms depilatories temporary and semi-permanent hair dyes hair mascaras anti-dandruff preparations dry shampoos heat-activated preparations
Color Cosmetics	emulsion foundations (oil-in-water, water-in-oil, water-in-silicone, mixed) anhydrous foundations and concealers transfer-resistant foundations and concealers fine-line-minimizing foundations and powders pressed powder wet/dry foundations eyeshadows (pressed and anhydrous) moisturizing lipsticks extended wear lipsticks transfer-resistant lipsticks lipglosses conditioning mascaras waterproof mascaras lash-extending, building, and curling mascaras brow mascaras liquid eyeliners blushers (pressed powder and anhydrous)

	edible body paint children's nail enamel
Ethnic Products	skin lightening creams, lotions, gels and serums facial and undereye lighteners skin clarifiers and brighteners dry skin emulsions hair relaxers facial depilatories hair styling pomades, gels, creams, sprays hair glossing and managing preparations make-up foundations pressed-powder blushes lipsticks
Spa Products	bath salts bath oils bath and shower cleansers scrub emulsions, gels, salts massage oils, gels, bars aromatherapy emulsions, balms, oils, salts clay and mud emulsions and masques preparations with incorporated encapsulates, herbs
Treatment, Hygiene, and OTC Drug Products	organic and inorganic sunscreen emulsions, sticks, gels, sprays, oils and solutions from SPF 2-50+ children's sunscreen products water- and sweat-resistant sunscreen products self-tanner emulsions, gels, sprays insect repellent emulsions, oils, sprays nail and cuticle treatment creams, gels, balms depilatories skin lighteners toothpastes mouthwashes vaginal lubricants skin protectant creams, lotions, mousses anti-acnes lotions, creams, make-up foundations, blotters and concealers medicated washes cleansing wipes anti-cellulite emulsions and gels lip balms oil-control preparations stick, roll-on, gel, and clear antiperspirants

topical analgesic emulsions, gels, sticks
tooth bleaching systems

**Fragrances and
Ancillaries**

perfumes, colognes, edp's, edt's, aftershaves
moisturizing fragrances
clear fragrance sticks
fragrance balms and pomades
bubble colognes
line-extension creams, lotions, gels, cleansers